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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/938,009 | 08/23/2001 | Clark M. Whitehead | P-188 | 1119 |

7590
Robert W. Stevenson
Cell Pathways, Inc.
702 Electronic Drive
Horsham, PA 19044

09/05/2003

EXAMINER

BAHAR, MOJDEH

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1617

DATE MAILED: 09/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/938,009

Applicant(s)

WHITEHEAD ET AL.

Examin r

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 30-37 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 & 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the first office action of December 4, 2002, along with exhibits A-C, submitted June 6, 2003 is acknowledged.

This application contains claims 30-37 and 39 drawn to an invention nonelected without traverse in Paper No. 4. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-29 and 38 are herein examined on the merits in so far as they read on the elected specie of compound 38.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claims 1 and 38 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. One of ordinary skill in the art cannot ascertain what degree of inhibition will be classified as "substantial". 20%? 50%? 80%? 99.99%?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-29 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sperl et al. (USPN 6,066,634) in view of Berkow et al. (*The Merck Manual of Medical Information*, Home Ed., 1997, p. 253)

Sperl et al. (USPN 6,066,634) teaches compound 38, the elected specie herein, in Example 1, see cols. 16-17, claims 1 and 28 in particular. Sperl et al. also teaches that its compounds are known PDE inhibitors and that they do not substantially inhibit COX-1 and COX-2, see col. 5, lines 19-30 and col. 28, line 49-col. 29, line 9. Sperl et al. also teaches the employment of its compounds in a method of treating autoimmune diseases, see col. 5, lines 8-18.

Sperl et al. does not particularly teach lupus erythematosus as an autoimmune disease.

Berkow et al. (*The Merck Manual of Medical Information*, Home Ed., 1997, p. 253) teaches that lupus erythematosus is an autoimmune disease.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ compound 38 in a method of treating lupus.

One of ordinary skill in the art would have been motivated to employ compound 38 in a method of treating lupus because compound 38 is known to be useful in methods of treating autoimmune diseases, a class of diseases which includes lupus.

Response to Arguments

Applicant's arguments filed June 6, 2003 have been fully considered but they are not persuasive. Applicant first argues against the rejection under 35 USC 112, stating that "substantially" is not vague and that patent claims need not be exacting. Note that it is well established patent law that the metes and bounds of the claim need to be clearly delineated. Applicant's employment of the relative adverb, i.e., "substantially" does not clearly delineate the claim since the Skilled Artisan would not know what degree of inhibition meets the limitation. In the specification on page 12 applicant discusses the term, but does not clearly define it. In order to demonstrate this ambiguity and vagueness consider the following questions: If a compound achieves 51% COX-1 or COX-2 inhibition, has it met the claim limitation? How about 1% inhibition? 25%? 10%?

Applicant's remarks and exhibits have been carefully considered, but are not persuasive to remove the obviousness rejection herein. Applicant argues that Sperl teaches a method of treating MS and RA, but not lupus. Note that Sperl teaches the treatment of autoimmune disorders broadly, see col. 5, line 16 in particular. Applicant further states that the pathogenesis of Lupus is different than those of MS and RA. According to applicant's own arguments and exhibits, RA and MS are two diseases with different pathogenesis. Yet the prior art, Sperl,

teaches the treatment of both with compound 38. Although these diseases have different pathogenesis and varying symptoms, they are both autoimmune diseases treatable by the same compound. The skilled artisan, in possession of the teachings of Sperl, would be motivated to employ compound 38 in treating any autoimmune disease, including lupus.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 on Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
August 25, 2003



SREENI PADMANABHAN
PRIMARY EXAMINER

9/4/03